

Subject: FR Notice Comments - 76FR29752 - Nominations of In Vitro Test Methods  
Date: Thursday, June 16, 2011 10:56 AM

Below is the result of your feedback form. It was submitted by  
( ) on Thursday, June 16, 2011 at 10:56:26

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Comment\_date: June 16, 2011

Prefix: Dr.

FirstName: Cheng

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Degree: Ph.D.

onBehalfOf: no

Title:

Department:

Company:

Country: USA

Comments: TO: NICEATM-ICCVAM Federal Register Notice

FOR: Nomination of In Vitro Test Methods for Detection and  
Quantification of Botulinum Neurotoxins and Detection of  
Non-Endotoxin Pyrogens; Data Request for Substances  
Evaluated by These Test Methods

The Polymerase Chain Reaction (PCR) provides high sensitivity and specificity in detection of a number of pathogenic microorganisms. A multiplex PCR assay has been developed to enable simultaneous and specific detection of more than one serotype of *Clostridium botulinum* neurotoxin gene including types A, B, E, and F. Such an assay would be a more sophisticated approach for sample, food and fecal, detection. Moreover, database such as gene-banks, software for designing primers and reaction conditions, PCR reagents/kits, PCR equipment etc. have been continuously upgraded with improved quality, accuracy, and practicability which makes the nucleic acid-

based assay remaining a valuable candidate for in vitro detection of Clostridium Botulinum neurotoxins.

Another newly developed method is the use of a simple and rapid affinity immunomatography column (AICC)-based tests, for detection of Clostridium botulinum neurotoxin types A, B, E and F and Escherichia coli 0157. The AICC assay has improved sensitivity and the feasibility to be more suitable for use in the field. [Jason Brunt etc. 2010. Applied and Environmental Microbiology, 76(13): 4143-4150].

I am the PHC (US Army Public Health Command) Representative for the ICCVAM. I would be glad to consult and provide my best advice on such issues based on my knowledge and experience from my long term professional practice.

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